REMARKS/ARGUMENTS

This Amendment is submitted in response to the Office Action dated April 13, 2005. Claims 7-11, 13-18, 20-31, 33 and 35-39 remain pending in the Application. Claim 12 has been canceled. Reconsideration and allowance is respectfully requested in view of the amendments made and the remarks made below.

1. The Specification

The Specification was objected to because of a typographical error on page 12, line 24. In response, the Applicant has amended the Specification to correct the typographical error by replacing the incorrect reference to Fig. 10 with the correct reference to Fig. 11, in accordance with the Examiner's suggestion. The Applicant respectfully submits that the objection has been overcome and requests notice that effect.

2. The Rejection under 35 U.S.C. § 112, First Paragraph

Claim 12 was rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Although the applicant does not agree with this rejection, the Applicant has canceled claim 12 in order to obviate the rejection. The Applicant submits that the cancellation of claim 12 obviates the rejection and requests notice to that effect.

3. Allowable Subject Matter

The applicant hereby acknowledges the Examiner's indication of allowable subject matter with appreciation. More specifically, the Examiner has allowed claims 15-18, 20-30, 31, 33, 35, 37, 38 and 39. The Applicant acknowledges that claims 11 and 13 have been objected to as being dependent upon a rejected base claim, but submits that they are in condition for allowance due to their dependence upon claim 7, which is allowable for the reasons set forth below.

4. The Rejection under 35 U.S.C. §102(b)

Claims 7 and 8 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,282,781 to Liprie (hereinafter "Liprie"). The Applicant respectfully submits that Liprie does not meet each and every limitation of independent claim 7 and thus does not anticipate either of claims 7-8 for the reasons given below. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The present invention, as claimed in claim 7, relates to a catheter useful for radiation treatment of a body. The catheter includes an elongate, flexible catheter body and a radioactive source housed within a cavity in the distal section of the catheter body. A portion of the catheter body is removable to provide access to the cavity wherein the radioactive source is housed. In this manner, a simple, easy to use catheter is provided that can locate the radioactive source very close to the treatment area. This is highly advantageous because the preferred forms of radioactive emitters for this application are beta-emitters, which are characterized by the fact that the radiation dose drops off sharply even a short distance from the emitter. As a result, it is very important to place the radiation emitter as close as possible to the treatment area to achieve the maximum effect of the radiation, to minimize unwanted irradiation of other organs, and to ensure a relatively even dose distribution throughout the treatment area in order to avoid hot spots that might lead to over radiation.

Liprie discloses a composite source wire 10, which is made from several components, including a flexible metal tube 12, a backbone wire 17, a radioactive core 25 and a plug 27. The process for making the composite source wire 10 is set out in detail in Liprie. The composite source wire 10 is disclosed as being useful for insertion into a patient through a separate catheter 50, 75. See e.g. col. 16, line 10, to col. 19, line 14 of Liprie.

In support of the rejection, the Examiner has taken the position that the flexible metal tube 12 of Liprie is a "catheter" and thus that Liprie anticipates claim 7 of the present application. However, it is the applicant's view that this interpretation of Liprie is incorrect since flexible metal tube 12 of Liprie is not a catheter when it is associated with the radioactive core 25, the composite source wire 10 of Liprie is not a catheter, and Liprie discloses that the

composite source wire 10, including the flexible metal tube 12, is designed for use with a catheter, and therefore it does not function as a catheter itself.

The Applicant submits that Liprie does not disclose having at least a portion of the catheter body being removable to provide access to a cavity wherein the radioactive source is housed. The Examiner has characterized the flexible metal tube component of the source wire 10 taught by Liprie as a "catheter." However, this is not correct. The flexible metal tube 12 of Liprie is not a catheter as the Examiner suggests.

First, Liprie itself clearly distinguishes between a catheter 50 or 75 and the source wire 10 and discloses that the source wire 10 is made for use by insertion into a patient through a catheter 50 (see col. 16, line 10, to col. 17, line 29 of Liprie) or a catheter 75 (see col. 18, line 54 to col. 19, line 14 of Liprie). The Applicant submits that the Examiner cannot simply take a component disclosed in Liprie, which Liprie clearly does not consider a catheter, and that clearly is not a catheter, and call it a "catheter". The Examiner is not pointing to Liprie's teaching of a catheter in order to make the rejection, but instead to a component of the source wire 10, which, according to Liprie, is a different structure than either of the catheters 50 and 75 discussed in Liprie.

Secondly, although the Examiner points to the flexible metal tube 12 of Liprie as being the catheter, it is the source wire 10 of Liprie that includes a radioactive source or pellet housed in a cavity in the distal end thereof. As can be seen from Figs. 1-2 of Liprie, the components of the source wire 10 include the tube 12, the backbone wire 17, the radioactive core 25 and the plug 27. Prior to insertion of radioactive core 25 into tube 12, backbone wire 17 is placed within tube 12. See col. 10, lines 43-47 of Liprie which disclose that when the radioactive core 25 is inserted, it abuts against the backbone wire 17, thus indicating that the backbone wire 17 must have already been inserted into tube 12 prior to insertion of radioactive core 25 into tube 12. This is important because source wire 10 is clearly not a "catheter" at the time that radioactive core 25 is inserted therein and thus does not anticipate claim 7 of the present application.

More specifically, after placing backbone wire 17 within tube 12, air spaces are removed between the two in order to avoid oxidation. See col. 9, lines 54-55 of Liprie. The procedure for removing the air spaces is described at col. 9., line 54 to col. 10, line 2. This step, "...creates a force fit between the tube and the backbone wire as the wall of the tube collapses tightly on the

wire and bonds itself at each of the crimps. Any air space which existed between the surface of the backbone wire and the interior surface of the tube prior to the drawing down of the tube onto the backbone wire is now completely eliminated, ..." See col. 10, lines 3-9 of Liprie. As a result of this step in the manufacturing process, tube 12 is no longer hollow, but rather virtually the entire length of the tube 12, except for a portion at the distal end which is intended to accommodate other components of the source wire 10, is completely filled by the backbone wire 17. See e.g. col. 9, lines 28-35 of Liprie. Accordingly, when the radioactive core 25 is inserted into the source wire 10 of Liprie, tube 12 is no longer a hollow tube, but rather the combination of tube 12 and backbone wire 17 has already been formed into a solid cylindrical object for virtually the entire length of tube 12, except for a small distal portion for housing the radioactive core 25 and plug 27.

Therefore, the tube 12 to which the examiner points, does not meet the definition of a catheter. The 4th edition of the American Heritage dictionary defines a catheter as "a hollow flexible tube for insertion into a body cavity, duct, or vessel to allow the passage of fluids or distend a passageway." When the radioactive core 25 of Liprie is inserted into tube 12, the tube 12 clearly does not meet the definition of catheter, since tube 12 is no longer hollow because it has already been completely filled for virtually its entire length by backbone wire 17, as demonstrated above. Thus, tube 12 of Liprie is used as a part in the construction of a composite source wire 10 that is solid over virtually its entire length. The only time at which tube 12 is hollow is in the preliminary stages of construction, before radioactive core 25 has been placed within tube 12. There is no hollow structure remaining after the tube 12 and backbone wire 17 are assembled together. Therefore, the device of Liprie including tube 12, is not a catheter as the Examiner suggests, but instead a source wire 10 that is intended to placed within a catheter for use within a human.

In summary, once tube 12 of Liprie has radioactive core 25 associated with it, it is no longer hollow, but rather is filled along virtually its entire length by backbone wire 17 to thereby form a cylindrical solid. Thus, tube 12 at this stage, does not meet the definition of catheter since it is not hollow, and it cannot function as a catheter since it cannot allow the passage of fluids or permit insertion of other devices via an internal lumen, since tube 12 of Liprie no longer includes an internal lumen or hollow passageway at this stage of construction. Therefore, the

composite source wire 10, of Liprie, does not meet each and every limitation of claim 7 of the present application since, at this stage of construction, it is not a catheter, nor does it have a catheter body.

Of course, at an earlier stage of construction, when tube 12 of Liprie is still hollow, the composite source wire 10 of Liprie still does not anticipate claim 7 of the present application because, at this stage, the composite source wire 10 of Liprie does not have a radioactive source housed within a cavity in the distal end thereof. Accordingly, even at an interim point in the construction of the composite source wire 10 of Liprie, when the tube 12 is still hollow, the composite source wire 10 does not meet each and every limitation of claim 7 of the present application because there is no radioactive core 25 present at this stage of the construction.

The Applicant is clearly claiming a catheter. As such, the claimed catheter has a hollow structure as is required by the dictionary definition of the term, "catheter." The claimed invention offers several advantages over the composite source wire of Liprie. First, the internal lumen formed by the hollow catheter can be used for other purposes such as drug delivery, fluid drainage or insertion of a guide wire. Also, the ability of the catheter of the present invention to accommodate the insertion of a separate guide wire in the internal lumen of the cathether offers two distinct advantages over Liprie. First, any guide wire can be used since it the guide wire does not contain the radioactive core, as in Liprie. Second, and more importantly, the positioning of the radioactive material in the catheter as in the present invention, rather than in the source wire as in Liprie, allows positioning of the radioactive source closer to the tissue to be treated since there is no requirement for an additional metal tube 12 located between the radioactive material and the tissue of the patient, in the device of the present invention, as there is in the structure of Liprie. Also, the device of Liprie suffers from the further disadvantage that metal tube 12 may shield some of the radiation from core 25, thereby altering the dose delivered to the patient from the radioactive core 25. In the present invention, no metal tube 12 is required and thus, this additional barrier between the radioactive source and the tissue of the patient can be eliminated, thereby eliminating the need to compensate for the adsorption of radiation that may occur by tube 12 of Liprie.

Therefore, the Applicant submits that Liprie's tube 12, when assembled into a complete source wire 10, including a radioactive core 25, does not meet the definition of a catheter, and therefore does not meet the limitations of claim 7 of the present application.

It should further be noted that the Applicant, in a July 2003 response to an office action, has already addressed Liprie. The Examiner viewed the remarks made by the Applicant at that time favorably and allowed claim 7 over Liprie. Claim 7 remains unchanged from that time.

For the foregoing reasons, the Applicant submits that claims 7 and 8 are allowable and requests notice to that effect.

6. The Rejections under 35 U.S.C. §103(a)

Claims 9, 10, and 36 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Liprie in view of U.S. Patent No. 6,589,502 to Coniglione et al. (hereinafter "Coniglione"). The Applicant submits that this combination does not meet each and every limitation of claims 9, 10, and 36.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 265 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

As noted above, the source wire 10 of Liprie is not a catheter since it is not hollow and thus does not have an internal lumen. Moreover, neither of the catheters 50, 75 disclosed in Liprie include a portion of the catheter body that is removable to provide access to a cavity wherein a radioactive source is housed. Coniglione does not cure either of these deficiencies of Liprie and, in fact, is relied on by the Examiner for an entirely different reason. Therefore, the Applicant submits that claims 9, 10, and 36 are in condition for allowance for at least the same reasons as given above for claims 7-8, and requests notice to that effect.

Claim 14 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Liprie. As noted above in section 5 of this paper, the catheter in Liprie does not have a portion of the catheter body that is removable to provide access to a cavity wherein the radioactive source is

housed. Also, the source wire 10 of Liprie is not a catheter since it is not hollow and thus does not have an internal lumen. Therefore, Liprie does not include the feature of claim 14 requiring a catheter or a catheter body. Therefore, the Applicant submits that claim 14 is in condition for allowance and requests notice to that effect.

7. Conclusion

Applicant has made an earnest effort to place this application in condition for allowance. If the Examiner feels that a telephone interview would expedite prosecution of this patent application, the Examiner is respectfully invited to telephone the undersigned at 215-599-0600.

Respectfully submitted,

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